

REMARKS

The present invention relates to a method for transforming dicot plants. More particularly, the method relates to the use of multiple shoot culture as the tissue into which a nucleic acid of interest is introduced, and from which transformed plants are regenerated. Claims 1, 14-16, 18, 22-29, and 51-64 are pending; claims 14-16 and 25-28 have previously been withdrawn; claims 2-13, 17, 19-21, and 30-50 have been cancelled; and claims 1, 18, 22-24, 29, and 51-64 have been examined and are the subject of the outstanding Office Action. Claims 22, 24, 29, and 64 have been amended in the present response, as shown above.

Applicants acknowledge the Examiner's withdrawal of the previous rejection of claims 1-13, 18-24, and 29 under 35 U.S.C. §103(a) over Tuli *et al.* in view of Rangan, as well as the enablement rejection of claims 1-13, 18-24, and 29.

Rejections Under 35 U.S.C. §112, First Paragraph

The Examiner has rejected claim 64 under 35 U.S.C. §112, first paragraph, "as failing to comply with the written description requirement. The Examiner states that "Claim 64 recites wherein said dicotyledonous plant tissue is from a plant of any family selected from *Curcubitaceae*, *Chenopodiaceae*, and *Asteraceae* while the specification only supports *Curcubitaceae*, and *Chenopodiaceae* as preferred source of transformable plant tissue." The Examiner also states that "the claims are drawn to NEW MATTER."

Applicants respectfully traverse. While the precise word "*Asteraceae*" does not appear in the specification, sunflower is a member of the family, and sunflower transformation using the method of the present invention is specifically disclosed. In fact, Applicants respectfully take the position that there is sufficient disclosure in the

instant specification to support the use of the method of the present invention for the transformation of all dicot species, including those in the family *Asteraceae*. However, in order to further prosecution, Applicants have made further amendments to the claims in order to address the Examiner's rejection, and respectfully request that this rejection be withdrawn.

Claims 1, 18, 22-24, 29, and 51-63 stand rejected under 35 U.S.C. §112, first paragraph, the Examiner stating that "the specification, while being enabling for a method of *Agrobacterium* mediated transformation of multiple shoot cultures of melon, watermelon, and squash from *Cucurbitaceae* and multiple shoot cultures of sugar beet from *Chenopodiaceae* and sunflower...does not reasonably provide enablement for non-*Agrobacterium*-mediated transformation methods..." The Examiner maintains his position from the previous Office Action, based upon the Kohli and Potrykus papers previously cited therein, and also upon the Taylor *et al.* DNA and Cell Biology Vol. 21 reference cited in the outstanding Office Action. The Examiner's position appears to be, in a nutshell, that there is an "unpredictability inherent in adapting transformation methods with a particular tissue culture method", and that this unpredictability is "shown in the number of multiple insertion events at the same locus in the genome of a transformed plant with a high degree of rearrangements of the transforming DNA in almost all the lines recovered" (citing Kohli *et al.*). The Examiner also states that even though DNA had been integrated, "the extent that the formation of chimeric structure would result in a phenotype is unpredictable." He also notes the possibility of gene silencing from multiple insertions, and cites Potrykus *et al.* in support of the statement that it is "well known in the art that direct DNA transfer transformation methods are inherently unpredictable and require rigorous testing..." Finally, the Examiner cites the Taylor *et al.* reference

as showing that “meristem bombardment gives rise to chimeric structures, multiple insertions, and low efficiencies of transformation requiring excessive effort to screen through a multitude of chimeric plants and plants having multiple insertions....” From the foregoing the Examiner concludes that “undue trial and error experimentation would be required to screen through the myriad of chimeric plants produced by a multitude of non-exemplified non-*Agrobacterium* methods of transformation...to find culturing and transformation conditions that would successfully recover a transformed plant with a non-chimeric transgene.”

Applicants respectfully traverse. Applicants believe that the Examiner’s argument is mis-directed, in that his position, and the evidence he presents in support of his position, speak to factors inherent in particular DNA delivery methods. In other words, by this time it is well understood in the art that *Agrobacterium*-mediated transformation typically gives cleaner DNA insertions, with fewer re-arrangements and fewer copies, particularly when compared to bombardment-mediated transformation. This does not, however, support the contention that simply because non-*Agrobacterium*-mediated DNA delivery methods can create a more complicated situation vis-à-vis screening and selecting for commercially desirable transformants, those methods would therefore require undue experimentation in the generation of those transformants.

In fact, in his conclusion the Examiner correctly states Applicants’ position; that the claimed invention is fully enabled by the instant disclosure, in that transformed plants will be generated by the claimed method, regardless of the DNA delivery method chosen. The screening required to choose commercially desirable events from among the transformed material may be more or less arduous, depending upon the DNA delivery method chosen, but that screening is not part of the claimed invention,

and in any event, even if it were, it would not amount to undue experimentation. In addition, as noted above, the need to screen out transgenic events having multiple insertions or chimeric insertions will necessarily be present due to the DNA delivery method chosen for use in the claimed invention, and not due to the claimed invention as a whole.

Furthermore, Applicants believe that this situation is analogous to that in *Ajinomoto Co., Inc. v. Archer Daniels Midland Co.*, 228 F.3d 1338, 56 U.S.P.Q.2d 1332 (Fed. Cir. 2000), in which it was found that a claimed process was enabled because it used conventional, well known genetic engineering techniques. In the present Office Action the Examiner has provided evidence showing that the need for screening of transformants exists, and that the level of screening can vary with the DNA delivery method (Agrobacterium-mediated, particle bombardment, electroporation, etc.) chosen by the scientist(s) performing the transformations. As was the case in *Ajinomoto*, practitioners of the transformation arts are prepared to carry out the identification/screening steps required following transformation to identify commercially desirable transformation events. Applicants respectfully submit that this does not amount to undue experimentation, and is in fact, as the references cited by the Examiner show, expected by those of skill in the art. Furthermore, the means for carrying out such screening are well known to the skilled practitioner. In view of the foregoing, Applicants respectfully submit that the instant rejection should be withdrawn.

Rejections under 35 U.S.C. §102(b)

Claims 22, 24, and 29 stand rejected under 35 U.S.C. §102(b) “as being anticipated by Bordas M. *et al.* Transgenic Research, 1997; Vol. 6, No.1, pagens 41-50. The Examiner characterizes Bordas *et al.* as teaching “transformed melon, melon

cells, and transgenic melon seeds therefrom...”, and goes on to state that the “prior art plants differ from the claimed plants, cells, and seeds only by their method of manufacture.” Applicants have amended Claims 22, 24, and 29, and respectfully submit that the amendments have addressed the basis for this rejection, and that the rejection should be withdrawn.

The Examiner has rejected Claim 23 under 35 U.S.C. § 102(b) as being anticipated by Dodds J. et al. Experiments in Plant Tissue Culture; Cambridge University Press, 1982; pages 98-106. The Examiner states that the claim relates to “both untransformed and transformed multiple shoot cultures produced during the method of Claim 1”, and also states that “Dodd teaches a method for culturing meristematic tissues of plants to form multiple shoot cultures....” The Examiner concludes that “the reference teaches all the limitations of Claim 23.”

Applicants respectfully traverse. Dodds does not, in fact, teach all of the limitations of Claim 23. The article discloses that apical meristem culture has been used for several types of plants, but the article does not disclose the plants specifically recited in Claim 1 (i.e., squash, melon, watermelon, sunflower, and sugarbeet). In view of the fact that these recited plants are not disclosed by Dodds, the reference cannot be deemed to anticipate the claimed invention. Therefore, Applicants respectfully submit that this rejection should be withdrawn.

Conclusion

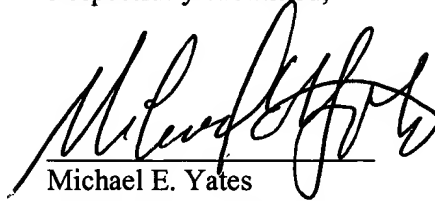
Applicants submit that the foregoing amendments and remarks address the grounds for rejection raised by the Examiner in the Office Action of February 17, 2004. Applicants respectfully request further prosecution on the merits and the allowance of the pending claims. If prosecution to allowance can be furthered by a

telephone call to the undersigned attorney for Applicants, the Examiner is encouraged to call 919-541-8587.

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Respectfully submitted,

A handwritten signature in black ink, appearing to read "Michael E. Yates", written over a horizontal line.

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